



Food and Drug Administration  
10903 New Hampshire Avenue  
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Silver Spring, MD 20993-0002

March 5, 2015

Biolase Incorporated  
Ms. Colleen Boswell  
Vice President of Regulatory Affairs and Quality Assurance  
4 Cromwell  
Irvine, California 92618

Re: K141975

Trade/Device Name: Waterlase iPlus S  
Regulation Number: 21 CFR 878.4810  
Regulation Name: Laser surgical instrument for use in general and  
plastic surgery and in dermatology  
Regulatory Class: Class II  
Product Code: GEX  
Dated: February 4, 2015  
Received: February 6, 2015

Dear Ms. Boswell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

  
Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.  
Director  
Division of Surgical Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K141975

Device Name

Waterlase iPlus S

### Indications for Use (Describe)

The Waterlase iPlus S is intended for use as a laser surgical instrument in the following medical specialties requiring the incision, excision, vaporization, ablation and coagulation of soft tissue: Dermatology/Plastic Surgery, Ear, Nose and Throat (ENT), Gastroenterology, General Surgery, Genitourinary/Urology, Gynecology, Ophthalmology, Oral/Maxillofacial Surgery, Podiatry, Pulmonary Surgery and Thoracic Surgery. It is indicated for the following expanded Indications for Use:

#### Dermatology/Plastic Surgery:

The following indications can be used with the Angled, Contra-Angled or Straight Handpieces:

Incision, excision, ablation, vaporization and coagulation of dermatologic tissues including epidermal nevi, telangiectasia, spider veins, actinic cheilitis, keloids, verrucae, skin tags, anal tags, keratoses, scar revision, debulking of benign tumors, decubitus ulcers, cysts, diagnostic biopsy and skin resurfacing and treatment of wrinkles.

#### Ear, Nose and Throat (ENT):

The following indications can be used with the Angled or Straight Handpieces:

ENT surgery in soft, mucosal, cartilaginous and bony tissue, including endosinus surgery, functional endoscopic sinus surgery, turbinate procedures (e.g. turbinoplasty, turbinectomy), dacryocystorhinostomy (DCR), ethmoidectomy, polypectomy, maxillary antrotomy, frontal sinusotomy, sphenoidotomy, hereditary hemorrhagic telangiectasias, septoplasty, lesions, polyps, cysts, hyperkeratosis, excision of carcinogenic tissue, oral leukoplakia.

#### Gastroenterology:

The following indications can be used with the Angled or Straight Handpieces:

Gastroenterologic surgery of soft tissue, including cholecystectomy, lysis of adhesions, appendectomy, biopsy, pylorostenotomy, benign and malignant lesions, rectal polyps of sigmoid colon, gall bladder calculi, biliary/bile duct calculi, benign and malignant neoplasm, polyps, colitis, ulcers, angiodysplasia, hemorrhoids, varices, esophagitis, esophageal ulcer, Mallory-Weiss tear, gastric ulcer, duodenal ulcer, non-bleeding ulcer, gastric erosions, colorectal cancer, gastritis, bleeding tumors, pancreatitis, vascular malformations, telangiectasias and telangiectasias of the Osler-Weber-Rendu disease.

#### General Surgery:

The following indications can be used with the Angled, Contra-Angled or Straight Handpieces:

Incision, excision, vaporization and coagulation of soft tissue during general surgical applications where skin incision, tissue dissection, excision of external tumors and lesions, complete or partial resection of internal organs, tumors and lesions, tissue ablation and/or vessel coagulation may be indicated.

#### Genitourinary/Urology:

The following indications are used with the Angled Handpieces:

Genitourinary surgery of soft tissue, including treatment of bladder, urethral and ureteral tumors, superficial urinary bladder tumors, invasive bladder carcinomas, urethral and penile hemangioma, urethral strictures, lesions of the external genitalia, urethra and anus, penis, scrotum, (includes condyloma acuminata, giant perineal condyloma and verrucous carcinoma), vulvar lesions, polyps and familial polyps of the colon, bladder neck obstructions.

The following indications are used with the Straight Handpieces:

Endoscopic transurethral incision of prostate, bladder neck incision of the prostate, laser ablation, enucleation and

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resection of prostate, hemostasis, vaporization and excision for treatment of benign prostatic hypertrophy.

Gynecology:

The following indications can be used with the Angled, Contra-Angled or Straight Handpieces:

Cervical intraepithelial neoplasia (CIN), herpes simplex, endometrial adhesions, cysts and condyloma.

Ophthalmology:

The following indications can be used with the Angled, Contra-Angled or Straight Handpieces:

General ophthalmic soft tissue surgical indications such as: Incision, excision, vaporization and coagulation of ocular tissue and tissue surrounding the eye and orbit.

Oral/Maxillofacial Surgery:

The following indications can be used with the Angled, Contra-Angled or Straight Handpieces:

Oral/dental procedures for incision, excision, ablation, vaporization and hemostasis of soft tissue during gingivoplasties, gingivectomies, frenectomies, benign and malignant lesion removal, biopsies, leukoplakia and fibrotomy.

Podiatry:

The following indications can be used with the Angled or Contra-Angled Handpieces:

Warts, plantar verrucae, large mosaic verrucae and matrixectomy.

Pulmonary Surgery:

The following indications can be used with the Angled or Straight Handpieces:

Open and endoscopic pulmonary surgery.

Thoracic Surgery:

The following indications can be used with the Angled or Straight Handpieces:

Surgical incision/excision, vaporization and coagulation of soft tissue during any thoracic surgery.

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Type of Use (*Select one or both, as applicable*)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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## **510(k) Summary**

### Submitter:

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Alicia Mszyca - Contact Person

Date Summary Prepared: February 2015

- Trade Name - *Waterlase iPlus S*
- Common Name - Er,Cr:YSGG Laser
- Classification Name - Laser surgical instrument for use in general and plastic surgery and in dermatology, per 21 CFR 878.4810
- Product Code - GEX

### Devices for Which Substantial Equivalence is Claimed:

- *Oculase MD*, Biolase, Inc., K052354
- *Waterlase MD Derm*, Biolase, Inc., K071734
- *Profile Multi-Platform System*, Sciton, Inc., K060033
- *Laserscope VELA Erbium:YAG Laser System and Accessories*, Laserscope, K971843

### Device Description

The *Waterlase iPlus S* system is an erbium, chromium, yttrium, scandium, gallium, garnet (ER,CR:YSGG) solid state laser that provides optical energy to the user-controlled distribution of atomized water droplets at 2.78  $\mu\text{m}$  (2780 nm). The laser consists of a cabinet which houses the power supply, the cooling system, micro-controller, laser, foot switch, and fiber optic for delivery of laser energy with the fiber optic handpiece. Various handpiece and tip types are available depending upon the clinician's preference for the different applications. The *Waterlase iPlus S* system utilizes direct laser energy either with or without water for cooling and hydration to perform soft tissue incision, excision, resection, ablation, vaporization, coagulation and hemostasis.

### Statement of Intended Use

The *Waterlase iPlus S* is intended for use as a laser surgical instrument in the following medical specialties requiring the incision, excision, vaporization, ablation and coagulation of soft tissue: Dermatology/Plastic Surgery, Ear, Nose and Throat (ENT), Gastroenterology, General Surgery, Genitourinary/Urology, Gynecology, Ophthalmology, Oral/Maxillofacial Surgery, Podiatry, Pulmonary Surgery and Thoracic Surgery. It is indicated for the following expanded Indications for Use:

**Dermatology/Plastic Surgery:*****The following indications can be used with the Angled, Contra-Angled or Straight Handpieces:***

Incision, excision, ablation, vaporization and coagulation of dermatologic tissues including epidermal nevi, telangiectasia, spider veins, actinic cheilitis, keloids, verrucae, skin tags, anal tags, keratoses, scar revision, debulking of benign tumors, decubitus ulcers, cysts, diagnostic biopsy and skin resurfacing and treatment of wrinkles.

**Ear, Nose and Throat (ENT):*****The following indications can be used with the Angled or Straight Handpieces:***

ENT surgery in soft, mucosal, cartilaginous and bony tissue, including endosinus surgery, functional endoscopic sinus surgery, turbinate procedures (e.g. turbinoplasty, turbinectomy), dacryocystorhinostomy (DCR), ethmoidectomy, polypectomy, maxillary antrotomy, frontal sinusotomy, sphenoidotomy, hereditary hemorrhagic telangiectasias, septoplasty, lesions, polyps, cysts, hyperkeratosis, excision of carcinogenic tissue, oral leukoplakia.

**Gastroenterology:*****The following indications can be used with the Angled or Straight Handpieces:***

Gastroenterologic surgery of soft tissue, including cholecystectomy, lysis of adhesions, appendectomy, biopsy, pylorostenotomy, benign and malignant lesions, rectal polyps of sigmoid colon, gall bladder calculi, biliary/bile duct calculi, benign and malignant neoplasm, polyps, colitis, ulcers, angiodysplasia, hemorrhoids, varices, esophagitis, esophageal ulcer, Mallory-Weiss tear, gastric ulcer, duodenal ulcer, non-bleeding ulcer, gastric erosions, colorectal cancer, gastritis, bleeding tumors, pancreatitis, vascular malformations, telangiectasias and telangiectasias of the Osler-Weber-Rendu disease.

**General Surgery:*****The following indications can be used with the Angled, Contra-Angled or Straight Handpieces:***

Incision, excision, vaporization and coagulation of soft tissue during general surgical applications where skin incision, tissue dissection, excision of external tumors and lesions, complete or partial resection of internal organs, tumors and lesions, tissue ablation and/or vessel coagulation may be indicated.

**Genitourinary/Urology:*****The following indications are used with the Angled Handpieces:***

Genitourinary surgery of soft tissue, including treatment of bladder, urethral and ureteral tumors, superficial urinary bladder tumors, invasive bladder carcinomas, urethral and penile hemangioma, urethral strictures, lesions of the external genitalia, urethra and anus, penis, scrotum, (includes condyloma acuminata, giant perineal condyloma and verrucous carcinoma), vulvar lesions, polyps and familial polyps of the colon, bladder neck obstructions.

***The following indications are used with the Straight Handpieces:***

Endoscopic transurethral incision of prostate, bladder neck incision of the prostate, laser ablation, enucleation and resection of prostate, hemostasis, vaporization and excision for treatment of benign prostatic hypertrophy.

**Gynecology:**

***The following indications can be used with the Angled, Contra-Angled or Straight Handpieces:***

Cervical intraepithelial neoplasia (CIN), herpes simplex, endometrial adhesions, cysts and condyloma.

**Ophthalmology:**

***The following indications can be used with the Angled, Contra-Angled or Straight Handpieces:***

General ophthalmic soft tissue surgical indications such as: Incision, excision, vaporization and coagulation of ocular tissue and tissue surrounding the eye and orbit.

**Oral/Maxillofacial Surgery:**

***The following indications can be used with the Angled, Contra-Angled or Straight Handpieces:***

Oral/dental procedures for incision, excision, ablation, vaporization and hemostasis of soft tissue during gingivoplasties, gingivectomies, frenectomies, benign and malignant lesion removal, biopsies, leukoplakia and fibrotomy.

**Podiatry:**

***The following indications can be used with the Angled or Contra-Angled Handpieces:***

Warts, plantar verrucae, large mosaic verrucae and matrixectomy.

**Pulmonary Surgery:**

***The following indications can be used with the Angled or Straight Handpieces:***

Open and endoscopic pulmonary surgery.

**Thoracic Surgery:**

***The following indications can be used with the Angled or Straight Handpieces:***

Surgical incision/excision, vaporization and coagulation of soft tissue during any thoracic surgery.

Summary of Technological Characteristics

Refer to the Table on the following pages.

<b>Descriptive Information</b>	<b>Waterlase iPlus S</b>	<b>Oculase MD (K052354)</b>	<b>Waterlase MD Derm (K071734)</b>	<b>Profile Multi-Platform System (K060033)</b>	<b>Laserscope VELA (K971843)</b>
<b>Company</b>	<b>Biolase, Inc.</b>	Biolase, Inc.	Biolase, Inc.	Sciton, Inc.	Laserscope
<b>Indications for Use</b>	<p>The <i>Waterlase iPlus S</i> is intended for use as a laser surgical instrument in the following medical specialties requiring the incision, excision, vaporization, ablation and coagulation of soft tissue: Dermatology/Plastic Surgery, Ear, Nose and Throat (ENT), Gastroenterology, General Surgery, Genitourinary/Urology, Gynecology, Ophthalmology, Oral/Maxillofacial Surgery, Podiatry, Pulmonary Surgery and Thoracic Surgery. It is indicated for the following expanded Indications for Use:</p> <p><b>Dermatology/Plastic Surgery:</b></p>	<p>The Oculase MD may be indicated for general ophthalmic soft tissue surgical indications such as: Incision, excision, vaporization and coagulation of ocular tissue and tissue surrounding the eye and orbit.</p>	<p>Use of the device is indicated for the incision, excision, ablation, vaporization and coagulation of dermatologic tissues including epidermal nevi, cheilitis, keloids, verrucae, skin tags, keratosis, scar revision, debulking of tumors, cysts, diagnostic biopsy and skin resurfacing.</p> <p>Use of the device is further indicated for the incision, excision, vaporization and coagulation of soft tissue during general surgical applications</p>	<p>2940nm Indications for Use: The Profile Multi-Platform and Accessories are designed for use in surgical applications requiring the excision, incision, ablation, vaporization, and coagulation of soft tissue, and for skin resurfacing. Soft tissue includes skin, subcutaneous tissue, striated and smooth tissue, muscle, cartilage, cartilage meniscus, calculi or fragments, mucous membrane, lymph vessels and nodes, organs and glands. Surgical specialties and applications include general surgery,</p>	<p>The Laserscope VELA Erbium:YAG Laser System and Accessories are intended for the surgical incision/excision, vaporization and coagulation of soft tissue. All soft tissue is included, such as skin, subcutaneous tissue, striated and smooth tissue, muscle, cartilage meniscus, mucous membrane, lymph vessels and nodes, organs and glands. Dermatology/Plastic Surgery: Indications include, epidermal nevi, telangiectasia, spider veins,</p>



<b>Descriptive Information</b>	<b>Waterlase iPlus S</b>	<b>Oculase MD (K052354)</b>	<b>Waterlase MD Derm (K071734)</b>	<b>Profile Multi-Platform System (K060033)</b>	<b>Laserscope VELA (K971843)</b>
	<p>Incision, excision, ablation, vaporization and coagulation of dermatologic tissues including epidermal nevi, telangiectasia, spider veins, actinic cheilitis, keloids, verrucae, skin tags, anal tags, keratoses, scar revision, debulking of benign tumors, decubitis ulcers, cysts, diagnostic biopsy and skin resurfacing and treatment of wrinkles.</p> <p><b><i>Ear, Nose and Throat (ENT):</i></b> ENT surgery in soft, mucosal, cartilaginous and bony tissue, including endosinus surgery, functional endoscopic sinus surgery, turbinate procedures (e.g. turbinoplasty, turbinectomy),</p>		<p>where skin incision, tissue dissection, excision of external tumors and lesions, complete or partial resection of internal organs, tumors and lesions, tissue ablation and/or vessel coagulation may be indicated.</p>	<p>plastic surgery, aesthetic surgery, dermatology, urology, gynecology, genitourinary, ENT, pulmonary, surgery, thoracic surgery, podiatry, oral &amp; maxillofacial surgery, ophthalmology (including oculoplasty), small and large joint arthroscopy, micro-discectomies and endoscopic procedures.</p> <p><u>Aesthetic Surgery</u> Skin resurfacing and treatment of wrinkles.</p> <p><u>Dermatology &amp; Plastic Surgery</u> Indications include, epidermal nevi, telangiectasia, spider veins, actinic cheilitis, keloids,</p>	<p>actinic cheilitis, keloids, verrucae, skin tags, anal tags, keratoses, scar revision, debulking benign tumors, decubitis ulcers and skin resurfacing.</p> <p><u>General Surgery</u> The Erbium:YAG laser is intended for the surgical incision/excision, vaporization and coagulation of soft tissue during any general surgery application where skin incision, tissue dissection, excision of external tumors and lesions, complete or partial resection of internal organs, tumors and lesions, tissue</p>

<b>Descriptive Information</b>	<b>Waterlase iPlus S</b>	<b>Oculase MD (K052354)</b>	<b>Waterlase MD Derm (K071734)</b>	<b>Profile Multi-Platform System (K060033)</b>	<b>Laserscope VELA (K971843)</b>
	<p>dacryocystorhinostomy (DCR), ethmoidectomy, polypectomy, maxillary antrotomy, frontal sinusotomy, sphenoidotomy, hereditary hemorrhagic telangiectasias, septoplasty, lesions, polyps, cysts, hyperkeratosis, excision of carcinogenic tissue, oral leukoplakia.</p> <p><b>Gastroenterology:</b> Gastroenterologic surgery of soft tissue, including cholecystectomy, lysis of adhesions, appendectomy, biopsy, pylorostenotomy, benign and malignant lesions, rectal polyps of sigmoid colon, gall bladder calculi, biliary/bile duct calculi, benign and malignant neoplasm, polyps,</p>			<p>verrucae, skin tags, anal tags, keratoses, scar revision, debulking benign tumors, decubitus ulcers. It is also used for laser assisted site preparation for hair transplantation.</p> <p><u>Gastroenterology</u> Gastroenterologic surgery of soft tissue, include: cholecystectomy, lysis of adhesions, appendectomy, biopsy, pylorostenotomy, benign and malignant lesions, rectal polyps of sigmoid colon, gall bladder calculi, biliary/bile duct calculi, benign and malignant neoplasm, polyps, colitis, ulcers,</p>	<p>ablation and/or vessel coagulation may be indicated.</p> <p>Genitourinary: Indications include lesions of the external genitalia, urethra and anus, penis, scrotum and urethra (includes condyloma acuminata, giant perineal condyloma and verrucous carcinoma), vulvar lesions, polyps and familial polyps of the colon.</p> <p><u>Gynecology</u> Indications include cervical intraepithelial neoplasia (CIN), herpes simplex, endometrial</p>

<i><b>Descriptive Information</b></i>	<i><b>Waterlase iPlus S</b></i>	<i><b>Oculase MD (K052354)</b></i>	<i><b>Waterlase MD Derm (K071734)</b></i>	<i><b>Profile Multi-Platform System (K060033)</b></i>	<i><b>Laserscope VELA (K971843)</b></i>
	<p>colitis, ulcers, angiodysplasia, hemorrhoids, varices, esophagitis, esophageal ulcer, Mallory-Weiss tear, gastric ulcer, duodenal ulcer, non-bleeding ulcer, gastric erosions, colorectal cancer, gastritis, bleeding tumors, pancreatitis, vascular malformations, telangiectasias and telangiectasias of the Osler-Weber-Rendu disease.</p> <p><b>General Surgery:</b> Incision, excision, vaporization and coagulation of soft tissue during general surgical applications where skin incision, tissue dissection, excision of external tumors and lesions, complete or partial</p>			<p>angiodysplasia, hemorrhoids, varices, esophagitis, esophageal ulcer, Mallory-Weiss tear, gastric ulcer, duodenal ulcer, non-bleeding ulcer, gastric erosions, colorectal cancer, gastritis, bleeding tumors, pancreatitis, vascular malformations, telangiectasias and telangiectasias of the Osler-Weber-Rendu disease. <u>General Surgery</u> The Er:YAG is intended for the surgical incision/excision, vaporization and coagulation of soft tissue during any general surgery application where</p>	<p>adhesions, cysts and condyloma. <u>ENT</u> Indications include ear, nose and throat lesions, polyps, cysts, hyperkeratosis, excision of carcinogenic tissue, oral leukoplakia. <u>Oral/Maxillofacial</u> Indications include benign oral tumors, oral and glossal lesions and gingivectomy. <u>Ophthalmology</u> Indications include soft tissue surrounding the eye and orbit and anterior capsulotomy. <u>Podiatry</u> Indications include warts, plantar verrucae,</p>

<b>Descriptive Information</b>	<b>Waterlase iPlus S</b>	<b>Oculase MD (K052354)</b>	<b>Waterlase MD Derm (K071734)</b>	<b>Profile Multi-Platform System (K060033)</b>	<b>Laserscope VELA (K971843)</b>
	<p>resection of internal organs, tumors and lesions, tissue ablation and/or vessel coagulation may be indicated.</p> <p><b><i>Genitourinary/Urology:</i></b> Genitourinary surgery of soft tissue, including treatment of bladder, urethral and ureteral tumors, superficial urinary bladder tumors, invasive bladder carcinomas, urethral and penile hemangioma, urethral strictures, lesions of the external genitalia, urethra and anus, penis, scrotum, (includes condyloma acuminata, giant perineal condyloma and verrucous carcinoma), vulvar lesions, polyps and familial polyps of</p>			<p>skin incision, tissue dissection, excision of external tumors and lesions, complete or partial resection of internal organs, tumors, tissue ablation and/or vessel coagulation.</p> <p><u>Genitourinary/Urology</u> Genitourinary surgery of soft tissue, including: treatment of bladder, urethral and ureteral tumors; superficial urinary bladder tumors; invasive bladder carcinomas; urethral and penile hemangioma; urethral strictures, lesions of the external genitalia; condylomas;</p>	<p>large mosaic verrucae and matrixectomy.</p>

<b><i>Descriptive Information</i></b>	<b><i>Waterlase iPlus S</i></b>	<b>Oculase MD (K052354)</b>	<b>Waterlase MD Derm (K071734)</b>	<b>Profile Multi- Platform System (K060033)</b>	<b>Laserscope VELA (K971843)</b>
	<p>the colon, bladder neck obstructions. Endoscopic transurethral incision of prostate, bladder neck incision of the prostate, laser ablation, enucleation and resection of prostate, hemostasis, vaporization and excision for treatment of benign prostatic hypertrophy.</p> <p><b><i>Gynecology:</i></b> Cervical intraepithelial neoplasia (CIN), herpes simplex, endometrial adhesions, cysts and condyloma.</p> <p><b><i>Ophthalmology:</i></b> General ophthalmic soft tissue surgical indications such as: Incision, excision, vaporization and coagulation of ocular tissue and tissue</p>			<p>bladder neck obstructions. Endoscopic transurethral incision of prostate, bladder neck incision of the prostate, laser ablation, enucleation and resection of prostate, hemostasis, vaporization and excision for treatment of benign prostatic hypertrophy.</p> <p><u>Gynecology</u> Indications include cervical intraepithelial neoplasia (CIN), herpes simplex, endometrial adhesions, cysts and condyloma.</p> <p><u>Ophthalmology</u></p>	

<i><b>Descriptive Information</b></i>	<i><b>Waterlase iPlus S</b></i>	<i><b>Oculase MD (K052354)</b></i>	<i><b>Waterlase MD Derm (K071734)</b></i>	<i><b>Profile Multi- Platform System (K060033)</b></i>	<i><b>Laserscope VELA (K971843)</b></i>
	<p>surrounding the eye and orbit.</p> <p><b><i>Oral/Maxillofacial Surgery:</i></b> Oral/dental procedures for incision, excision, ablation, vaporization and hemostasis of soft tissue during gingivoplasties, gingivectomies, frenectomies, benign and malignant lesion removal, biopsies, leukoplakia and fibrotomy.</p> <p><b><i>Podiatry:</i></b> Warts, plantar verrucae, large mosaic verrucae and matrixectomy.</p> <p><b><i>Pulmonary Surgery:</i></b> Open and endoscopic pulmonary surgery.</p> <p><b><i>Thoracic Surgery:</i></b> Surgical incision/excision,</p>			<p>Indications include soft tissue surrounding the eye and orbit and anterior capsulotomy.</p> <p><u>Oral/</u> <u>Maxillofacial</u> Indications include oral/dental procedures for incision, excision, ablation, vaporization and hemostasis of soft tissue during gingivoplasties, gingivectomies, frenectomies, benign and malignant lesion removal, biopsies, leukoplakia and fibrotomy.</p> <p><u>ENT Surgery</u> ENT surgery in soft, mucosal, cartilaginous and bony tissue,</p>	

<b><i>Descriptive Information</i></b>	<b><i>Waterlase iPlus S</i></b>	<b>Oculase MD (K052354)</b>	<b>Waterlase MD Derm (K071734)</b>	<b>Profile Multi- Platform System (K060033)</b>	<b>Laserscope VELA (K971843)</b>
	vaporization and coagulation of soft tissue during any thoracic surgery.			including: endosinus surgery, functional endoscopic sinus surgery, turbinate procedures (e.g. turbinoplasty, turbinectomy), dacryocysto-rhinostomy (DCR), ethmoidectomy, polypectomy, maxillary antrotomy, frontal sinusotomy, sphenoidotomy, hereditary hemorrhagic telangiectasia, septoplasty. <u>Podiatry</u> Indications include warts, plantar verrucae, large mosaic verrucae and matrixectomy. <u>Pulmonary Surgery</u> Open and endoscopic pulmonary surgery.	

<i>Descriptive Information</i>	<i>Waterlase iPlus S</i>	<i>Oculase MD (K052354)</i>	<i>Waterlase MD Derm (K071734)</i>	<i>Profile Multi-Platform System (K060033)</i>	<i>Laserscope VELA (K971843)</i>
				<u>Thoracic Surgery</u> Intended for the surgical incision/excision, vaporization and coagulation of soft tissue during any thoracic surgery.	
<i>Laser Classification</i>	<b>IV (4)</b>	IV (4)	IV (4)	IV (4)	IV (4)
<i>Operating Voltage</i>	<b>100 VAC ± 10% 230VAC ± 10%</b>	100 VAC ± 10% 230VAC ± 10%	100 VAC ± 10% 230VAC ± 10%	200 - 240 VAC	220 VAC
<i>Laser Medium</i>	<b>ER,CR:YSGG</b>	ER,CR:YSGG	ER,CR:YSGG	ER:YAG	ER:YAG
<i>Wavelength</i>	<b>2.78µm (2780nm)</b>	2.78µm (2780nm)	2.78µm (2780nm)	2940nm	2940nm
<i>Current Frequency</i>	50 - 60 Hz	50 - 60 Hz	50 - 60 Hz	50 - 60 Hz	Not available
<i>Max Output Power</i>	<b>10 watts ± 20%</b>	8 watts ± 20%	8 watts ± 20%	45 watts ± 20%	45 watts
<i>Power Mode</i>	<b>Pulsed Free Running</b>	Pulsed Free Running	Pulsed Free Running	Not available	Not available
<i>Cooling</i>	<b>Water</b>	Water	Water	Not available	Not available
<i>Pulse Duration</i>	<b>60µs, 700µs</b>	60µs, 700µs	60µs, 700µs	100 µs - 5ms	Not available
<i>Aiming Beam</i>	<b>Laser Diode, max 1mW, 635nm Class I</b>	Laser Diode, max 1mW, 635nm Class I	Laser Diode, max 1mW, 635nm Class I	Laser Diode, max 5mW, 650nm ± 5nm Class II	Not available



<i>Descriptive Information</i>	<b><i>Waterlase iPlus S</i></b>	<b>Oculase MD (K052354)</b>	<b>Waterlase MD Derm (K071734)</b>	<b>Profile Multi- Platform System (K060033)</b>	<b>Laserscope VELA (K971843)</b>
<i>Materials</i>	<b>Medical grade plastics, steel, stainless steel, aluminum, brass, and electronic parts and components</b>	Medical grade plastics, steel, stainless steel, aluminum, brass, and electronic parts and components	Medical grade plastics, steel, stainless steel, aluminum, brass, and electronic parts and components	Medical grade plastics, steel, stainless steel, aluminum, brass, and electronic parts and components	Medical grade plastics, steel, stainless steel, aluminum, brass, and electronic parts and components

### Non-Clinical Test Data

Safety testing of the *Waterlase iPlus S* was successfully completed according to IEC 60601-1 – Medical electrical equipment, Part 1: General requirements for safety and essential performance, IEC 60601-1-2 Medical electrical equipment- Part 1-2: General requirements for basic safety and essential performance –collateral standard: electromagnetic compatibility- requirements and tests, IEC 60825-1 Safety of laser products - Part 1: Equipment classification and requirements, IEC 60601-2-22 Medical electrical equipment- Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment.

Software verification and validation was conducted due to modifications of layout of the Graphical User Interface resulting from the expanded indications for use. The results demonstrate that the *Waterlase iPlus S* performs according to specifications and functions intended.

No other performance testing was conducted since the purpose of this 510(k) is to only expand the Indications for Use from the previous 510(k) clearances under 510(k) Nos.: K101658 and K122368. All indications included in this 510(k) have already been cleared by the FDA for equivalent medical devices manufactured by Biolase, Inc., Sciton, Inc. and Laserscope.

### Clinical Test Data

Clinical testing was not conducted on this device.

### Conclusion

Based upon the comparison of the *Waterlase iPlus S* with the same device, *Waterlase iPlus, Profile Multi-Platform System* and *Laserscope VELA* previously cleared by the FDA, the clinical performance of the *Waterlase iPlus S* for the Indications for Use described above is deemed to be substantially equivalent to the legally-marketed predicate devices, the *Waterlase iPlus, Profile Multi-Platform System* and *Laserscope VELA*.